

Food and Drug Administration  
Center for Food Safety and Applied Nutrition  
Office of Special Nutritionals

ARMS#

13380



8 - OTHER

**000001**

FROM

- RECORD OF DEATH

NAME: [REDACTED] SEX: M BIRTH DATE: [REDACTED]  
ADDRESS: [REDACTED] PHONE: [REDACTED]  
PLACE OF DEATH: [REDACTED]  
DATE: 2/27/99 TIME: 8:30:00 AM  
REPORTED BY: DR. [REDACTED] PHONE: [REDACTED]  
RELATIONSHIP: ATTENDING MD  
DATE REPORTED: 2/27/99 TIME: 8:38:00 AM  
Recent Trauma: N Aspiration: N Drug Abuse: N Iatrogenic Complications: N  
At SCENE: [REDACTED] PHONE: [REDACTED]  
RELATIONSHIP:  
DOCTOR: DR. [REDACTED] PHONE: [REDACTED]  
ADDRESS: [REDACTED]

CAUSE OF DEATH: OTHER CONDITIONS:  
INTRACRANIAL HTN  
SUBARACHNOID HEMORRHAGE  
CEREBRAL ANEURYSM

LAST DATE OF ATTENDANCE: 2/27/99  
SOURCE OF INFORMATION: ATTENDING MD

**HISTORY:**

THE SUBJ, AN 18 Y/O MALE W/ NO SIGNIFICANT MEDICAL HX, EXPIRED AT THE [REDACTED] ACC TO DR. [REDACTED] ATTENDING MD, IN THE EVENING OF 2/26/99, THE SUBJ REPORTEDLY SUFFERED SEIZURE-LIKE ACTIVITY AND COLLAPSED ON HIS WAY TO THE GYM. HE WAS BIBA TO [REDACTED] WHERE CT SCANS REVEALED A MASSIVE SUBARACHNOID HEMORRHAGE. ICP MONITOR WAS PLACED AND DRAINAGE WAS PERFORMED. URINE TOX SCREEN UPON ADMISSION TO [REDACTED] WAS NEGATIVE. ON 2/27/99 AT 0400 HRS, THE SUBJ WAS TRANSFERRED EMERGENTLY TO [REDACTED] WHERE ICP MONITOR WAS > 100. DESPITE PLACEMENT OF A VENTRICULAR DRAIN, THE SUBJ WAS DECLARED CLINICALLY BRAIN DEAD, AND WAS PRONOUNCED AT 0830 HRS, SAME DATE. DR. [REDACTED] STATED THAT THERE WAS NO SUSPICION OF ANY DRUG ABUSE OR TRAUMA CONTRIBUTING TO THE SUBJ'S DEMISE. DR. [REDACTED] WILL SIGN THE D/C AS STATED ABOVE. A CONSENT TO POST IS PENDING CONSULTATION W/ FAMILY.

INVESTIGATOR: [REDACTED] REVIEWED BY:

000002

FROM

TOXICOLOGY DIVISION

Name:

Case No.

Date Received:

Date Completed

03-02 -99

SPECIMENS RECEIVED: BLOOD ( ) URINE ( ) VITREOUS ( ) CSF ( ) BILE ( )  
KIDNEY ( ) STOMACH ( ) LIVER ( ) AM SAMPLES ( X )

TESTS PERFORMED	BLOOD	URINE	BILE	VITREOUS	LIVER	AM BLD	AMU
COMPOUNDS	UG/ML	UG/ML	UG/ML	UG/ML	UG/G		

ETHANOL  
VOLATILES  
AMOBARBITAL  
PENTOBARBITAL  
SECOBARBITAL  
PHENOBARBITAL  
CHLORDIAZEPOXIDE  
DIAZEPAM  
NORDIAZEPAM  
AMPHETAMINE  
METHAMPHETAMINE  
DIPHENHYDRAMINE  
MEPERIDINE  
PHENCYCLIDINE  
LIDOCAINE  
COCAINE  
BENZOYLECGONINE  
FLUOXETINE  
CLOMIPRAMINE  
DOXEPIN  
PROPOXYPHENE  
NORPROPOXYPHENE  
AMITRIPTYLINE  
NORTRIPTYLINE  
IMIPRAMINE  
DESIPRAMINE  
METHADONE  
METHADONE METABOLITE  
ZOLOFT  
MORPHINE  
CODEINE  
HYDROCODONE  
DIPHENYLHYDANTOIN  
CARBOXYHEMOGLOBIN  
EPHEDRINE  
NOREPHEDRINE  
OTHER  
EVIDENCE:

N.D.*	3.03
N.D.*	2.95

\* N.D. = NOT DETECTED; \* Q.N.S. - QUANTITY NOT SUFFICIENT ; P=PERIPHERAL ; C-CENTRAL

000003

FROM [REDACTED]

According to a treating physician from [REDACTED] the patient had gone to the Gym with a friend and was about ten minutes into a work-out when he began to complain of a severe headache. He returned to the friends house, where he showered while the friend fixed some food-thinking that the headache was because the patient had not eaten. The friend then found him in bed, initially thinking that he was asleep, then realizing that there was a severe problem.

At [REDACTED] the patient was obtunded, with a normal blood pressure but with CNS signs. A CT scan showed a massive bleed, probably arising from the area of the circle of willis. Although not proven, the [REDACTED] physician opined that there was probably a congenital berry aneurysm.

Contact with Dr. [REDACTED] (Poison control center) indicated that they didn't have anything on "ultimate orange, but contact with the FDA (Ms. Connie Hardy) indicated that they have a few cases, none proven to be cause and effect. Only one of a "stroke" and the patient is alive.

000004

Additional information regarding [REDACTED]

I talked to the treating physician at [REDACTED] I responded to [REDACTED] and reviewed the CT scans. I also recovered the admission blood and urine specimens from the laboratory. Those specimens were tested for ephedrine. There was no detectable drug level in the blood. The urine contained ephedrine at the level of 3.03 micrograms/mL, and 2.95 micrograms/mL of nor-ephedrine.

I also discussed this case with Dr. [REDACTED] of Poison control and Dr. Love of the FDA. Dr. Love told me of her agencies concern of the potential relation of the use of ephedrine and complications, including intracerebral bleeds.

Upon review of the case, this has more of the appearance of a young man with a probable berry aneurysm that ruptured during lifting exercise. The location and distribution of the blood suggests that origin, but without an autopsy or more definitive clinical study, that diagnosis simply remains the most likely and logical

Jurisdiction is not asserted in this case, since there is insufficient evidence to support an un-natural death. I left the phone number of the funeral home with Dr. Love, in the event that the FDA wishes to pursue the matter further on their own.

[REDACTED]

000005